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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,863	08/26/2003	John A. Delyani	C-3258	3765

7590 10/12/2006

PHARMACIA CORPORATION
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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,863	DELYANI ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part), 2-26, 46-52, 60, and 72-74, drawn to a method to treat, prevent, and inhibit pathogenic changes of an artery resulting from vascular injury employing an aldosterone antagonist, classified in class 514, subclass 171, 173, and 174.

II. Claims 27-37, 53, 57, 61, 64-67 drawn to a method of treating, preventing or inhibiting restenosis of an artery resulting from vascular injury employing an aldosterone antagonist, classified in class 514, subclass 171, 173, and 174.

III. Claims 38, 39, 54, 58, and 62, drawn to a method of treating, preventing or inhibiting vascular constrictive remodeling resulting from vascular injury employing an aldosterone antagonist, classified in class 514, subclass 171, 173, and 174.

IV. Claims 40-45, 55, 59, and 63, drawn to a method of treating, preventing or inhibiting vascular collagen accumulation resulting from vascular injury employing an aldosterone antagonist, classified in class 514, subclass 171, 173, and 174.

V. Claims 1 and 68 (in part) and 69, drawn to a method of treating, preventing or inhibiting pathogenic changes of an artery resulting from vascular injury employing the administraion of aldosterone antagonist and

an angiotensin II antagonist, classified in class 514, subclass 171, 173, 174, 381, 297, and 394.

VI. Claims 1 and 68 (in part) and 70, drawn to drawn to a method of treating, preventing or inhibiting pathogenic changes of an artery resulting from vascular injury employing the administraion of aldosterone antagonist and an angiotensin converting enzyme inhibitor, classified in class 514, subclass 171, 173, 174, 212.07, 423, 221, 91, 392, and 412.

VII. Claims 1 and 68 (in part) and 71, drawn to drawn to a method of treating, preventing or inhibiting pathogenic changes of an artery resulting from vascular injury employing the administraion of aldosterone antagonist, an angiotensin converting enzyme inhibitor and a diuretics, classified in class 514, subclass 171, 173, 174, 212.07, 423, 221, 91, 392, 412, 471, 568, and 571.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case the different inventions have different functions. The invention of Group I functions to treat, prevent or inhibit pathogenic change of an artery employing an aldosterone antagonist; the invention of Group II functions to treat, prevent or inhibit restenosis of an

artery employing an aldosterone antagonist; the invention of Group III functions to treat, prevent or inhibit vascular constrictive remodeling of an artery employing an aldosterone antagonist; and the invention of Group IV functions to treat, prevent or inhibit pathogenic change of an artery employing an aldosterone antagonist. They all function to treat different medical conditions. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I, V, VI, and VII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case the different inventions have different modes of operation. The invention of Group I operates by the employment of an aldosterone antagonist; the invention of Group V operates by the employment of an aldosterone antagonist and an angiotensin II antagonist; the invention of Group VI operates by the employment of an aldosterone antagonist and an angiotensin converting enzyme inhibitor; the invention of Group VII operates by the employment of an aldosterone antagonist, an angiotensin converting enzyme inhibitor and a diuretic. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Claims 1-50, 60-65, and 67-74 generic to a plurality of disclosed patentably distinct species comprising angiotensin II antagonist, angiotensin converting enzyme inhibitor, diuretics, and/or aldosterone antagonists. For example, if the angiotensin II antagonist is losartan, it is clssified in class 514, subclass 381; if the angiotensin II antagonist is eprosartan, it is clssified in class 514, subclass 397; if the angiotensin II antagonist is telmisartan, it is clssified in class 514, subclass 394.

For angiotensin converting enzyme inhibitors, if the angiotensin converting enzyme inhibitor is enalapril, it is classified in class 514, subclass 423; if the angiotensin converting enzyme inhibitor is cilazepril, it is classified in class 514, subclass 221; if the angiotensin converting enzyme inhibitor is fosinopril, it is classified in class 514, subclass 91; if the angiotensin converting enzyme inhibitor is imidapril, it is classified in class 514, subclass 392.

For diuretics, if the compound is furosemide, it is classified in class 514, subclass 471; if the compound is bumetanide, it is classified in class 514, subclass 568; if the compound is ethacrynic acid, it is classified in class 514, subclass 571.

For aldosterone antagonists, if the compound is spironolactone, it is classified in class 514, subclass 173; if the compound is compound #10 in Table 1 in the specification, it is classified in class 514, subclass 174.

Due to the different natures and search field for each disease state and the structural differences of the compounds encompassed by the claims, searching for all the species impose an undue burden to the office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of one aldosterone antagonist if Group I, II, III, or IV is elected or one single disclosed combination of active agents if Group V, VI, or VII is elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617